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PATENT TRADEMARK OFFICE

Docket No: 2094/1E285US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kevin M. GORMAN, David R. PATTERSON, Jeffrey M. LINNEN and Keming SONG

Serial No.: 09/494,332 Art Unit: 1655

Confirmation No.: 3281

Filed: January 28, 2000 Examiner: J. GOLDBERG

For: OLIGONUCLEOTIDE PRIMERS FOR EFFICIENT MULTIPLEX DETECTION OF HEPATITIS C VIRUS (HCV) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND METHODS OF USE THEREOF

SECOND DECLARATION OF KEVIN M. GORMAN UNDER 37 C.F.R. § 1.132

Hon. Commissioner of Patents and Trademarks
Washington, DC 20231

S I R:

I, Kevin M. GORMAN, hereby declare and state as follows:

1. I am a citizen of the United States of America and am more than 21 years of age.

2. I make these statements in furtherance of a previous Declaration Under 37 C.F.R. § 1.132 (the "first Gorman Declaration") that I made in connection with the above-captioned patent application and which was signed by me on February 8, 2002.

3. I am one of the named inventors in the above-captioned patent application. I make the following averments for myself and on behalf of my co-inventors.

4. I am also a named inventor in co-pending U.S. patent application Serial No. 09/493,353 filed January 28, 2000 ("the '353 application"). A copy of the '353 application is attached to this Declaration at Tab 1.

5. The specification of the '353 application describes certain experiments, that were carried out by my co-inventors and myself or by others working under our supervision and control, relating to oligonucleotide primers referred to in both the '353 and this application as C131F25 and C294R25. These oligonucleotide primers are identical to oligonucleotide primers that are also described in the instant application and recited in its pending claims.

6. Specifically, Example 1 starting on page 19 of the '353 application describes experiments where HCV was detected in clinical samples from Brazilian and Egyptian patients carrying certain HCV genotypes that are relatively rare in the United States. The experiments compared HCV detection rates in those clinical samples

using: (i) PCR assays that used particular primers described in the '353 application, including the primers C131F25 and C294R25; and (ii) a commercial PCR assay, known as the Roche AMPLICOR assay, that used primers derived from the same region of the HCV genome as C131F25 and C294R25.

7. A comparison between the results obtained using (i) the primer pair C131F25 and C294R25, and (ii) the Roche AMPLICOR assay is provided in Table 5 on page 24 of the '353 application. All of the primers of the '353 invention demonstrated superior sensitivity when compared to the Roche AMPLICOR assay. In particular, five samples that tested HCV-negative using the Roche AMPLICOR assay tested HCV-positive using the C131F25 and C294R25 primer pair.

8. A second series of experiments is also described, starting at page 25 of the '353 application, where 150 blood plasma samples from Brazil were tested using both the Roche AMPLICOR assay and using the primers described in the '353 application (including the C131F25 and C294R25 primer pair). The blood plasma samples that were tested in these experiments had been previously determined to be positive for HCV antibody. Negative control samples, consisting of both negative plasma and water (containing no RNA) were also prepared, interspersed throughout the clinical blood plasma samples, and tested.

9. A comparison of the results from these plasma samples using (i) the primer pair C131F25 and C294R25, and (ii) the Roche AMPLICOR assay is provided in Table 7 on page 26 of the '353 application. Briefly, the 131F25/C294R25 primer pair exhibited superior sensitivity relative to the Roche AMPLICOR assay, and

detected HCV in four blood plasma samples that tested HCV-negative using the Roche AMPLICOR assay. All of the negative control samples tested HCV-negative in both assays.

10. Example 2, starting at page 26 of the '353 application, describes a third set of experiments that tested the sensitivity of HCV-specific primers described in that application, including the C131F25/C294R25 primer pair. Specifically, three patient samples were diluted based on theoretical copy numbers of HCV RNA in the samples. The samples were then tested for HCV using: (i) the primer pairs C131F25 and C294R25; and (ii) the Roche AMPLICOR assay.

11. The results from this third set of experiments are provided in Table 9 on page 27 of the '353 application. In all three sets of diluted patient samples, the assay employing the C131F25/C294R25 primer pair displayed greater sensitivity than the Roche AMPLICOR assay.

12. I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false

statements may jeopardize the validity of the instant application or of any patent issued therefrom.

Respectfully submitted,

Dated: January 27, 2003

Kevin M. Gorman

Attachment:

Tab 1: U.S. patent application Serial No. 09/493,353 as filed January 28, 2000.